

larger and smaller dimensions are also contemplated by the present invention. In some embodiments, the thickness is 1.5 millimeters or less, the length is 5 centimeters or less, and the width is 1.25 centimeters or less. In other embodiments, the solid support comprises plastic. In yet other embodiments, the collection site comprises an absorbent material.

The present invention provides a variety of analyte detection systems. For example, the present invention provides assay tests for use in detecting analytes including, but not limited to, alcohol, glucose, ketones, cancer markers (e.g., prostate-specific antigen [PSA], epidermal growth factor receptor [EGFR], cancer antigen CA 15-3), cortisol, serotonin, 5-hydroxytryptophane, methadone, cocaine, cannabinoids (e.g., 11-carboxy- Δ^9 -tetrahydrocannabinolic acid), opiates, caffeine, phenytoin, primidone, carbamazepine, antibodies, pathogens (e.g., *P. gingivalis*, *Chlamydia* organisms, *Streptococcus* organisms, organisms that cause common infectious diseases such as the flu, measles, etc., *Bacillus anthracis* and other organisms that may be used in biological warfare or terrorism, etc.), melatonin, insulin, DHEA sulfate, aldosterone, testosterone, progesterone, androstenedione, estriol, estrone, urea, uric acid, ammonia, calcium, cholesterol, lactoferrin, growth factors (e.g., EGF, NGF, IGF-1), haliperidol, theophylline, cotinine, estradiol, salicylic acid, acetaminophen, nitrazepam, clobazam, amphetamine, quinine, lithium, antibiotics (e.g., penicillin and tetracycline), vitamins, minerals, toxins, anti-oxidants, monosodium glutamate (MSG), components of food products (e.g., peanuts and/or tree nuts), proteins and nucleic acids (e.g., DNA and RNA), including host and non-host (e.g., pathogenic) proteins and nucleic acids.

In some embodiments, the reaction site comprises an enzyme that reacts directly or indirectly with the analyte to initiate a reaction resulting in the generation of a detectable signal. In some embodiments, the reaction site further comprises one or more competitors, wherein the one or more competitors are configured to prevent the reaction site from producing the detectable signal until the one or more competitors are substantially depleted or otherwise prevent the detectable signal from being substantially detectable unless a threshold concentration of analyte is present in a sample. It is contemplated that, in some embodiments, multiple competitors are used,

each with a different threshold level, such that the reaction site produces detectable signals at two or more particular concentrations of test samples. However, it should be noted that, in some embodiments, multiple threshold levels are obtained with the use of a single competitor or no competitors. Indeed, any desired detection configuration can be used. For example, a first detection event may occur at a desired threshold level of analyte, followed by a gradient detection read-out above the threshold level (e.g., a first detected color is observed above a concentration of 0.04%, followed by a gradual increase in a color from concentrations above 0.04%). In some embodiments, the reaction site further comprises one or more stabilizers (e.g., compounds that increase the shelf-life of the reaction site in response to moisture, light [e.g., ultra-violet light], air, and the like). In yet other embodiments, the reaction site comprises two or more reaction components, wherein the two or more reaction components of the reaction site are separated by one or more breakable barriers. In some embodiments, the reaction site is enclosed in a protective encasement.

In some embodiments, the enzyme used in the reaction site is an oxidase or reductase that results in the production of oxidized and reduced reaction products. The oxidized or reduced reaction products result in the generation of a detectable signal through a subsequent oxidation/reduction reaction (e.g., a reaction that results in a color change caused by a change in the oxidation state of a chromogen). Thus, in some embodiments, any analyte containing a chemical moiety capable of undergoing a change in oxidation state (e.g., analytes containing alcohol, ketone, aldehyde, and/or carboxylic acid groups) finds use with the present invention. The present invention provides non-toxic, non-irritant, and/or non-carcinogenic colorimetric detection systems for use in the reaction site, wherein the color is produced in response to an enzyme (e.g., oxidases, peroxidases, dehydrogenases) that generates oxidized and reduced reaction products (e.g., hydrogen peroxide, NADP⁺, etc.). These detection systems find use as oral assay tests.

In some embodiments, the assay test employs one or more antibodies that bind to an antigen, wherein the antigen is the analyte to be detected or wherein the antigen is detectable (e.g., generated) when the analyte to be detected is present in a sample.

In some preferred embodiments, a colorimetric system is used to indicate the binding between the antibody and the antigen. These detection systems find use as oral assay tests.

5 In some embodiments of the present invention, the first and second portions of the solid support are separated by a hinge. In other embodiments, the first and second portions of the solid support are separated by a breakable barrier. In yet other embodiments, the collection site is slidably attached to the solid support. In some embodiments, the collection site and reaction site are provided at the same location.

10 In some preferred embodiments, the system further comprises a protective encasement, wherein the diagnostic device is enclosed in the protective encasement.

In some preferred embodiments of the present invention, the diagnostic device further comprises a second reaction site attached to a third portion of the solid support, wherein the second reaction site produces a second detectable signal, with the second detectable signal indicating a sufficient volume of the test sample (*e.g.*, saliva sample).

15 In some embodiments of the present invention, the detection test assay comprises a "test strip" with a thickness X cm, a width Y cm, and a length Z cm, wherein $X * Y * Z$ is less than 12 cm^3 , preferably less than 2 cm^3 and more preferably less than 1 cm^3 , although larger and smaller dimensions are also contemplated by the present invention. In some embodiments, the thickness is 0.5 millimeters or less, the length is 6.5 centimeters or less, and the width is 5 millimeters or less.

20 The present invention further provides a system comprising a plurality of test assays for analyzing a sample for the presence of an analyte, said system comprising a plurality of assay tests within a delivery system, said delivery system preventing the assay tests from being exposed to the environment and wherein the delivery system is small (*e.g.*, wallet sized, pocket sized, credit card sized). In some embodiments the small delivery system comprises a width (at the widest portion) of X cm, a length (at the longest portion) of Y cm, and a thickness (at the thickest portion) of Z cm, wherein $X * Y * Z$ is less than 100 cm^3 (*e.g.*, 30 cm^3 or less, 20 cm^3 or less, 10 cm^3 or less). In some preferred embodiments, the delivery system is flat (*e.g.*, comprising one or more flat panels). In some such embodiments, the ratios of $X:Z$ and $Y:Z$ are